

Proposed revisions to the Declaration of Helsinki

Paving the way for globalization in research

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A front-page article in the *New York Times* in June described a horrifying scenario: Cornell University researchers, using National Institutes of Health (NIH) funds, have followed dozens of Haitians infected with the HIV for years without providing the protease inhibitors and other medications that have revolutionized the care of patients with HIV.¹ The researchers actually turned down an offer of free medication from the French government. This study was in clear contravention of the 1996 Declaration of Helsinki, which requires that "In any medical study, every patient...should be assured of the best proven diagnostic and therapeutic method."²

For decades, the Declaration has provided an internationally accepted yardstick by which the ethical nature of research can be judged. But the research industry has mounted a coordinated, multipronged assault on these principles, endangering the health of research participants, particularly poor people and those in developing countries. In a revised draft considered by the World Medical Association, the phrase "that would otherwise be available to him or her" was appended to the principle quoted above.³ This would open up the entire developing world (and, potentially, poorer sectors of the industrialized world) to research protocols that would be deemed unacceptable in the United States. The draft also permits the use of placebos if the outcome of interest is not "death or disability," regardless of the existence of effective therapy. Although not adopted, this draft articulates where the research industry hopes the Declaration will go.

This is just the first prong of the assault. Reacting to a 1997 controversy over the failure of US government-funded researchers to provide zidovudine to all HIV-positive pregnant women in vertical transmission studies in Africa and Asia,^{4,5} researchers recently released a so-called consensus statement on future HIV perinatal research. Despite the demonstrated effectiveness of short (and hence substantially less expensive) courses of antiretroviral agents in reducing perinatal HIV transmission in developing world settings, the researchers concluded that in future studies "a no-intervention controlled design may be ethically justified in host countries where there is no antiretroviral therapy currently available."⁶

The next prong comes from the Joint United Nations Programme on HIV/AIDS, which has been developing ethical guidelines for the conduct of HIV vaccine trials. After lengthy consultation and meetings on 5 continents, no consensus was reached on several key issues.⁷ UNAIDS is now poised simply to release the document as a UNAIDS

policy document. That document will likely be based on a previous draft⁸ that would also permit suboptimal treatment of participants who became HIV-infected during the trial, even though the researchers plan to follow such individuals prospectively for years.

Finally, the Council of International Organizations for Medical Sciences (CIOMS)⁹ document is also undergoing revision, and the most recent version is said to recommend changes similar to those proposed for the Declaration of Helsinki, although the CIOMS draft has not circulated beyond the working committee.

To date, the efforts to dilute accepted ethical principles have featured academic or government scientists prominently; the pharmaceutical industry has remained safely off-stage. If these changes are enacted, the pharmaceutical companies and their colleagues in the world of human experimentation corporations (formerly contract-research organizations) will be among the first to exploit the opportunity offered by enhanced access to "drug-naïve"¹⁰ patients, a descriptor used (in a possibly unintended double entendre) on the website of Quintiles, an international clinical trials firm. These organized assaults come at a propitious time: improvements in communication and transportation make research in developing countries more practical than ever. They are the ethical equivalents of the deregulation, low wages, exploitative working conditions, and reduced environmental protections that are the inevitable consequence of globalization. Where Nike leads, must the NIH follow?

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